UNITED STATES DISTRICT COURT EASTERN DISTRICT OF MICHIGAN SOUTHERN DIVISION

BRENDA BANSALE, On Behalf of Herself and All Others Similarly Situated, and ROBERT BANSALE,)))
Plaintiffs, v.)) CIVIL ACTION NO: 2:12-cv-14559-RHC-PJK)
NEW ENGLAND COMPOUNDING PHARMACY, INC.,) JURY DEMANDED)
Defendant.)
ALYSON OLIVER (P55020) Attorney for Plaintiff Oliver Law Group PC 950 W. University Ste. 200 Rochester, MI 48307 Phone (248) 352-6556 notifications@oliverlg.com	DAVID L. CAMPBELL (P66287) CARMEN M. BICKERDT (P62874) Bowman and Brooke LLP Attorneys for New England Compounding Pharmacy, Inc. 41000 Woodward Avenue, Suite 200 East Bloomfield Hills, MI 48034 248.205.3300 ph / 248.205.3399 fx david.campbell@bowmanandbrooke.com carmen.bickerdt@bowmanandbrooke.com

NEW ENGLAND COMPOUNDING PHARMACY, INC.'S ANSWER, AFFIRMATIVE DEFENSES, RESERVATION OF RIGHTS, AND RELIANCE ON JURY DEMAND

Defendant, NEW ENGLAND COMPOUNDING PHARMACY, INC., by and through its undersigned counsel, hereby answers Plaintiffs' Complaint as follows:

RESPONDING TO INTRODUCTION

Defendant is not required to respond to the allegations of the Introduction that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.

RESPONDING TO BACKGROUND

- 1. Defendant admits that it compounded and dispensed certain preparations, but denies the remaining allegations in Paragraph 1.
- 2. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 2.
- 3. Defendant admits that it compounded and dispensed a preparation known as methylprednisolone acetate ("MPA"). Defendant is not required to respond to the remaining allegations of Paragraph 3 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations.
- 4. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 4.
- 5. Defendant admits that it voluntarily recalled certain of its compounded and dispensed preparations. Defendant lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations in Paragraph 5.
- 6. NECC admits that it voluntarily recalled certain of its compounded and dispensed preparations. NECC further states that, at all relevant times, it held a pharmacy license. Defendant lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations in Paragraph 6.
- 7. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 7.
- 8. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 8.

- 9. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 9.
- 10. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 10.
- 11. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 11.
- 12. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 12.
- 13. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 13 relating to Plaintiff's treatment at Michigan Pain Specialists. Defendant is not required to respond to the remaining allegations of Paragraph 13 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.
- 14. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 14.
- 15. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 15.
- 16. Defendant is not required to respond to the allegations of Paragraph 16 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.

RESPONDING TO JURISDICTION AND VENUE

17. Defendant is not required to respond to the allegations of Paragraph 17 that set forth legal conclusions. However, to the extent such allegations may be construed against

Defendant, Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations.

- 18. Defendant is not required to respond to the allegations of Paragraph 18 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations.
- 19. Defendant is not required to respond to the allegations of Paragraph 19 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations.
- 20. Defendant admits that, from time to time, it has in the past compounded and dispensed preparations in Michigan. Defendant is not required to respond to the remaining allegations of Paragraph 20 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations.

RESPONDING TO ALLEGATIONS CONCERNING PLAINTIFF

- 21. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 21.
- 22. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 22.

RESPONDING TO ALLEGATIONS CONCERNING DEFENDANT

23. Defendant admits that it compounded and dispensed certain preparations, including MPA. Defendant is not required to respond to the remaining allegations of Paragraph

- 23 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.
- 24. Defendant admits that it is a Massachusetts corporation with a principal place of business located at 697 Waverly Street, Framingham Massachusetts.

RESPONDING TO [PUTATIVE] CLASS ALLEGATIONS

- 25. Defendant is not required to respond to the allegations of Paragraph 25 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations.
- 26. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 26.
- 27. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 27.
- 28. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 28.

RESPONDING TO CLASS PREREQUISITE ALLEGATIONS

- 29. Defendant denies the allegations in Paragraph 29.
- 30. Defendant denies the allegations in Paragraph 30.
- 31. Defendant denies the allegations in Paragraph 31.
- 32. Defendant denies the allegations in Paragraph 32.
- 33. Defendant denies the allegations in Paragraph 33.
- 34. Defendant denies the allegations in Paragraph 34.
- 35. Defendant denies the allegations in Paragraph 35.

- 36. Defendant denies the allegations in Paragraph 36.
- 37. Defendant denies the allegations in Paragraph 37.
- 38. Defendant denies the allegations in Paragraph 38.

ANSWERING COUNT I

- 39. Defendant repeats and restates the responses of the preceding paragraphs as if fully set forth herein.
- 40. Defendant admits that it compounded and dispensed a preparation known as MPA. Defendant is not required to respond to the remaining allegations of Paragraph 40 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.
- 41. Defendant is not required to respond to the allegations of Paragraph 41 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.
- 42. Defendant is not required to respond to the allegations of Paragraph 42 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.
- 43. Defendant is not required to respond to the allegations of Paragraph 43 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.
- 44. Defendant is not required to respond to the allegations of Paragraph 44 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.

- 45. Defendant is not required to respond to the allegations of Paragraph 45 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.
- 46. Defendant is not required to respond to the allegations of Paragraph 46 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.
- 47. Defendant is not required to respond to the allegations of Paragraph 47 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.
- 48. Defendant is not required to respond to the allegations of Paragraph 48 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.
- 49. Defendant is not required to respond to the allegations of Paragraph 49 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.
- 50. Defendant is not required to respond to the allegations of Paragraph 50 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.
- 51. Defendant is not required to respond to the allegations of Paragraph 51 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.

- 52. Defendant is not required to respond to the allegations of Paragraph 52 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.
- 53. Defendant is not required to respond to the allegations of Paragraph 53 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.
- 54. Defendant is not required to respond to the allegations of Paragraph 54 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.
- 55. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 55 relating to Plaintiffs' medical condition, medical history, or alleged injuries. Defendant is further not required to respond to the allegations of Paragraph 55 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.
- 56. Defendant is not required to respond to the allegations of Paragraph 56 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.

Defendant denies entitlement to the relief requested in the Complaint.

ANSWERING COUNT II

57. Defendant repeats and restates the responses of the preceding paragraphs as if fully set forth herein.

- 58. Defendant is not required to respond to the allegations of Paragraph 58 that set forth legal conclusions or duties. However, to the extent such allegations may be construed against Defendant, they are denied.
- 59. Defendant is not required to respond to the allegations of Paragraph 59 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.
- 60. Defendant is not required to respond to the allegations of Paragraph 60 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.
- 61. Defendant is not required to respond to the allegations of Paragraph 61 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.
- 62. Defendant is not required to respond to the allegations of Paragraph 62 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.
- 63. Defendant is not required to respond to the allegations of Paragraph 63 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.
- 64. Defendant is not required to respond to the allegations of Paragraph 64 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.

- 65. Defendant is not required to respond to the allegations of Paragraph 65 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.
- 66. Defendant is not required to respond to the allegations of Paragraph 66 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.
- 67. Defendant is not required to respond to the allegations of Paragraph 67 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.

Defendant denies entitlement to the relief requested in the Complaint.

ANSWERING COUNT III

- 68. Defendant repeats and restates the responses of the preceding paragraphs as if fully set forth herein.
- 69. Defendant is not required to respond to the allegations of Paragraph 69 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.
- 70. Defendant is not required to respond to the allegations of Paragraph 70 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.
- 71. Defendant is not required to respond to the allegations of Paragraph 71 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.

Defendant denies entitlement to the relief requested in the Complaint.

ANSWERING COUNT IV

- 72. Defendant repeats and restates the responses of the preceding paragraphs as if fully set forth herein.
- 73. Defendant is not required to respond to the allegations of Paragraph 73 that set forth legal duties. However, to the extent such allegations may be construed against Defendant, they are denied.
- 74. Defendant is not required to respond to the allegations of Paragraph 74, including subsections a through i, that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.
- 75. Defendant is not required to respond to the allegations of Paragraph 75 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.
- 76. Defendant is not required to respond to the allegations of Paragraph 76 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.
- 77. Defendant is not required to respond to the allegations of Paragraph 77 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.
- 78. Defendant is not required to respond to the allegations of Paragraph 78 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.

- 79. Defendant is not required to respond to the allegations of Paragraph 79 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.
- 80. Defendant is not required to respond to the allegations of Paragraph 80 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.
- 81. Defendant is not required to respond to the allegations of Paragraph 81 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.
- 82. Defendant is not required to respond to the allegations of Paragraph 82 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.

Defendant denies entitlement to the relief requested in the Complaint.

ANSWERING COUNT V

- 83. Defendant repeats and restates the responses of the preceding paragraphs as if fully set forth herein.
- 84. Defendant is not required to respond to the allegations of Paragraph 84 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.
- 85. Defendant is not required to respond to the allegations of Paragraph 85 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.

- 86. Defendant is not required to respond to the allegations of Paragraph 86 that set forth legal duties. However, to the extent such allegations may be construed against Defendant, they are denied.
- 87. Defendant is not required to respond to the allegations of Paragraph 87 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.
- 88. Defendant is not required to respond to the allegations of Paragraph 88 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.
- 89. Defendant is not required to respond to the allegations of Paragraph 89 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.
- 90. Defendant is not required to respond to the allegations of Paragraph 90 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.
- 91. Defendant is not required to respond to the allegations of Paragraph 91 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.

Defendant denies entitlement to the relief requested in the Complaint.

ANSWERING COUNT VI

92. Defendant repeats and restates the responses of the preceding paragraphs as if fully set forth herein.

- 93. Defendant is not required to respond to the allegations of Paragraph 93 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.
- 94. Defendant is not required to respond to the allegations of Paragraph 94 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.
- 95. Defendant is not required to respond to the allegations of Paragraph 95 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.
- 96. Defendant is not required to respond to the allegations of Paragraph 96 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.
- 97. Defendant is not required to respond to the allegations of Paragraph 97 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.
- 98. Defendant is not required to respond to the allegations of Paragraph 98 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.
- 99. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 99 relating to Plaintiffs' medical condition, medical history, or alleged injuries. Defendant is further not required to respond to the allegations of Paragraph 99 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.

Defendant denies entitlement to the relief requested in the Complaint.

ANSWERING COUNT VII

- 100. Defendant repeats and restates the responses of the preceding paragraphs as if fully set forth herein.
- 101. Defendant is not required to respond to the allegations of Paragraph 101 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.
- 102. Defendant is not required to respond to the allegations of Paragraph 102 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.
- 103. Defendant is not required to respond to the allegations of Paragraph 103 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.
- 104. Defendant is not required to respond to the allegations of Paragraph 104 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.
- 105. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 105 relating to Plaintiffs' medical condition, medical history, or alleged injuries. Defendant is further not required to respond to the allegations of Paragraph 105 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.

RESPONDING TO WHEREFORE CLAUSE

Defendant denies entitlement to the relief requested in the Complaint.

ANSWERING COUNT VIII

- 106. Defendant repeats and restates the responses of the preceding paragraphs as if fully set forth herein.
- 107. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 107.
- 108. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 108 relating to Plaintiff's loss of consortium, society, companionship or other economic or noneconomic losses. Defendant is further not required to respond to the allegations of Paragraph 108 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.

ANSWERING COUNT IX

- 109. Defendant repeats and restates the responses of the preceding paragraphs as if fully set forth herein.
- 110. Defendant is not required to respond to the allegations of Paragraph 110 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.
- 111. Defendant is not required to respond to the allegations of Paragraph 111 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.
- 112. Defendant is not required to respond to the allegations of Paragraph 112, including subsections a through i, that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.

- 113. Defendant is not required to respond to the allegations of Paragraph 113 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.
- 114. Defendant is not required to respond to the allegations of Paragraph 114 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.

Defendant denies entitlement to the relief requested in the Complaint.

ANSWERING COUNT X

- 115. Defendant repeats and restates the responses of the preceding paragraphs as if fully set forth herein.
- 116. Defendant is not required to respond to the allegations of Paragraph 116 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.
- 117. Defendant is not required to respond to the allegations of Paragraph 117 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.
- 118. Defendant is not required to respond to the allegations of Paragraph 118 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.
- 119. Defendant is not required to respond to the allegations of Paragraph 119 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.

RESPONDING TO PRAYER FOR RELIEF

120. Defendant denies entitlement to the relief requested in paragraphs a–f of the Prayer for Relief contained in the Complaint.

DEFENSES AND AFFIRMATIVE DEFENSES

During the course of litigation, a number of defenses and/or affirmative defenses may become available to the defendant. To the extent any of the following are available and may apply, notice is hereby given of the following:

- 1. The Complaint fails to state a claim or cause of action cognizable in law or equity.
- 2. The Complaint fails to allege a cognizable claim for breach of any applicable standard for the practice of pharmacy.
- 3. The Complaint may be barred, in whole or in part, by applicable statutes of limitation and/or repose.
 - 4. Standing to sue may be lacking on all or some of the claims.
- 5. This action may be dismissed and/or transferred under the doctrine of *forum non conveniens*.
 - 6. No injury has been sufficiently stated or proven.
- 7. The Complaint fails to sufficiently identify a preparation compounded or dispensed by the defendant.
- 8. The alleged injuries or damages may not have been proximately caused by the defendant.
- 9. The alleged injuries or damages may have been proximately caused by one or more unforeseeable, independent intervening or superseding events beyond the control of and unrelated to the conduct of the defendant.

- 10. The injuries or damages alleged may have been caused or contributed to by preexisting and/or unrelated medical, genetic and/or environmental conditions, diseases or illnesses.
- 11. The injuries or damages alleged may have been caused or contributed to by an idiosyncratic reaction to any compounded or dispensed preparation.
- 12. The preparation alleged to have caused injury or damage was dispensed and compounded in accordance and consistent with the state of the art in the industry.
- 13. The alleged injuries or damages may have been caused or contributed to by known risks inherent in certain medical procedures, and which are otherwise open and obvious, or that were voluntarily undertaken, with full knowledge and consent. Such risks were therefore assumed and accepted through consenting and engaging in said medical procedures.
- 14. Adequate warnings and information were available to the medical profession, including any prescribing or administering healthcare provider.
- 15. The preparations compounded and dispensed were intended to be used and administered only by licensed health care practitioners in the care and treatment of their patients. Such licensed health care practitioners were knowledgeable, learned intermediaries and sophisticated users in treating patients and performing medical procedures.
- 16. The alleged injuries or damages were caused by the unforeseeable misuse, abuse, or inappropriate handling of the preparation by others, which was unforeseeable to the defendant.
- 17. The preparation may have been modified, altered or changed from the condition in which it was originally compounded and dispensed, which modification, alteration or change caused or contributed to the alleged injuries or damages.
- 18. Claims under applicable state law fail to state any claim upon which relief can be granted.

- 19. To the extent that comments (g), (h), (i), (j) and (k) of Section 402A of the Restatement (Second) of Torts and Comment (b) of Section 6 of the Restatement (Third) of Torts are applicable, such provisions may be relied upon in defense of this action.
 - 20. Damages, if any, have not been appropriately mitigated.
- 21. The injuries or damages alleged may have been caused in whole or in part by the purported contributory negligence and/or culpable conduct of others and not as a result of any conduct on the part of the defendant. Recovery, if any, should be limited or reduced in proportion to the parties' purported comparative fault and in accordance with applicable state law.
- 22. Any liability of the defendant is limited to the allowable percentage of alleged culpability found and should be further limited by virtue of the fault of other parties or entities (appearing and non-appearing, named and un-named) and in accordance with applicable state law.
- 23. The injuries or damages alleged may be attributable to several causes and, accordingly, should be apportioned among the various causes according to the respective contribution of each cause of the harm sustained, if any.
- 24. The claim should be diminished in whole or in part by any amount paid or fairly allocable to any party that has settled or may settle.
- 25. Any verdict or judgment must be reduced by those amounts which have or will, with reasonable certainty, replace or indemnify, in whole or in part, for any past or future claimed loss, including from any collateral sources such as insurance, disability, social security, worker's compensation or employee benefit programs.

- 26. Any liability for non-economic loss is limited in accordance with the alleged relative culpability of all persons or entities contributing to the total liability for alleged non-economic loss, including named parties and others over whom personal jurisdiction could have been obtained with due diligence.
- 27. The claims are barred, in whole or in part, based upon a balancing of risk and utility factors.
 - 28. The alleged damages were not caused by any failure to warn.
 - 29. No warranty, express or implied, was made.
 - 30. Claims for breach of express or implied warranty are barred for lack of privity.
 - 31. Claims for breach of warranty are barred for lack of reliance.
- 32. Pursuant to Rule 9(b) of the Federal Rules of Civil Procedure, the Complaint fails to adequately plead allegations of fraud, fraudulent concealment and/or misrepresentation.
- 33. Notice was not received of any claimed breach of warranty, including any notice that may have been required under the Uniform Commercial Code, Section 2-607(e), or by any other applicable federal or state law.
- 34. Punitive damages are barred because applicable procedures fail to provide specific limits or standards as to the amount of any such award.
- 35. Punitive damages are barred because applicable procedures do not provide sufficient notice of the type of conduct upon which an award of punitive damages may be based.
- 36. Punitive damages are barred because applicable procedures fail to provide clear, consistent standards for appellate review of an award of punitive damages.
- 37. Punitive damages are barred because applicable procedures may allow for the consideration of inappropriate evidence, such as wealth, in assessing punitive damages.

- 38. An award of punitive damages as alleged would violate one or more of the protections provided by the United States Constitution and/or by any other applicable state statute or constitution or law.
- 39. Defendant denies all allegations not expressly admitted and specifically reserves all affirmative or other defenses that it may have against the purported class. It is not necessary at this time for NECC to delineate such defenses against the purported class because no class has been certified and the putative class members are not parties to this litigation.
- 40. The claims of some members of the purported class are barred because they never suffered the alleged injury.
- 41. The allegations of the Complaint do not adequately set forth the elements required to proceed with a representative action under applicable state and/or federal laws. The putative class representatives have thus failed to state a claim upon which they or any other purported class member could proceed.
 - 42. The Complaint does not provide a legally sufficient or sustainable class definition.
 - 43. The allegations of the Complaint do not satisfy the prerequisite of numerosity.
 - 44. The allegations of the Complaint do not satisfy the prerequisite of ascertainability.
 - 45. The allegations of the Complaint do not satisfy the prerequisite of commonality.
 - 46. The allegations of the Complaint do not satisfy the prerequisite of typicality.
 - 47. The allegations of the Complaint do not satisfy the prerequisite of adequacy.
 - 48. The allegations of the Complaint do not satisfy the prerequisite of superiority.

WHEREFORE, Defendant demands Judgment of this Court:

a. dismissing the Complaint against it, with prejudice;

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b. awarding to Defendant the costs, expenses, and fees associated with defending

this action; and

c. granting such other and further relief, both legal and equitable, that the Court

deems just and proper.

RESERVATION OF RIGHTS

Defendant reserves the right to list additional affirmative defenses as may be appropriate

upon completion of its investigation and discovery and throughout trial.

RELIANCE UPON JURY DEMAND

Defendant relies on the jury demand filed by Plaintiffs in this matter and demands a jury

trial on all issues.

Dated: December 18, 2012

BOWMAN AND BROOKE LLP

BY: /s/ David L. Campbell

DAVID L. CAMPBELL (P66287)

CARMEN M. BICKERDT (P62874)

Attorneys for New England Compounding Pharmacy,

Inc.